

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Jonathan S. Stamler, Andrew J. Gow and David J. Singel

Application No.:

10/066,320

Group Art Unit:

1654

Filed:

January 31, 2002

Examiner:

Gupta, Anish

Confirmation No.:

1921

Title:

METHOD FOR DETERMINING PHYSIOLOGICAL EFFECTS

OF HEMOGLOBIN

## RECEIVED

JUL 1 7 2003

TECH CENTER 1600/2900

## INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 Sir: This Information Disclosure Statement is submitted: under 37 CFR 1.129(a), or (First/Second submission after Final Rejection) [X] under 37 CFR 1.97(b), or (Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination). under 37 CFR 1.97(c) together with either: a Statement under 37 CFR 1.97(e), as checked below, or a \$180.00 fee under 37 CFR 1.17(p), or (After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first) under 37 CFR 1.97(d) together with: [ ] a Statement under 37 CFR 1.97(e), as checked below, and

[ ] under 37 CFR 1.97(i):

a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper. (Filed after payment of issue fee)

Staten	nent Unc	er 3/ CFR 1.9	<u>7(e)</u>	
[]	001/ 001	nmunication fr	tion contained in this Information Disclosure Statement was first cited in from a foreign patent office in a counterpart foreign application not more or to the filing of this Information Disclosure Statement; or	n ;
[]	knowle	inication from edge of the und	on contained in this Information Disclosure Statement was cited in a a foreign patent office in a counterpart foreign application, and, to the dersigned, after making reasonable inquiry, no item of information contactlosure statement was known to any individual designated in 37 CFR ee months prior to the filing of this Information Disclosure Statement.	iinec
Stater	nent Unc	ler 37 CFR 1.7	(Patent Term Adjustment) Applies to original applications (other than design) filed on or after May 29,	2000
[]	commi	inication from t received by a	tion contained in the Information Disclosure Statement was cited in a a foreign patent office in a counterpart application and this communicatiny individual designated in § 1.56(c) more than thirty days prior to the ion Disclosure Statement.	tion
[X]	Enclos	ed herewith is	form PTO-1449:	
	[X]	Copies of the	cited references are enclosed.	
	[ ]	Application N	ed references are enclosed except those entered in prior application, U.S. No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The ear ontains copies of the cited references.]	lier
	[]	The listed refecounterpart for	Ferences were cited in the enclosed International Search Report in a preign application.	
	[ ]	The "concise under 37 CFF	explanation" requirement (non-English references) for reference(s) [ R 1.98(a)(3) is satisfied by:	]
		[ ] the ex	aplanation provided on the attached sheet.	
		[ ] the ex	xplanation provided in the Specification.	
		[ ] submi	ission of the enclosed International Search Report.	
		[ ] submi	ission of the enclosed English-language version of a foreign Search Rep r foreign Office Action.	ort
		[ ] the en	nclosed English language abstract.	

[]	A	pplic	ant requests that the following	non-published pending applic	cations be considered:		
Examiner's Initials							
			U.S. Patent Application No. [	], by [inventor(s)], filed [	], Docket No.: [ ]		
			U.S. Patent Application No. [	], by [inventor(s)], filed [	], Docket No.: [ ]		
			U.S. Patent Application No. [	], by [inventor(s)], filed [	], Docket No.: [ ]		
			Examiner	Date			
	[	]	A copy of each above-cited ap	oplication, including the curre	ent claims, is enclosed.		
	[	]	A copy of each above-cited ap those entered in prior applicat 35 U.S.C. 120 is claimed.	oplication, including the curre ion, U.S. Application No. [	ent claims, is enclosed, excep ], to which priority unde		
The Ex	xar 1ce	niner s we	r is requested to return a copy or re considered with the next offi	f the above list of pending ap ce communication.	plications indicating which		
It is re	qu	ested	that the information disclosed	herein be made of record in t	his application.		
Metho	d o	of pay	yment:				
[ ]	A	chec	ck for the fee noted above is ene panying Reply. A copy of this	closed, or the fee has been inc Statement is enclosed.	cluded in the check with the		
[]		lease nclos	e charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is sed.				
[X]	P	lease	charge any deficiency in fees a	and credit any overpayment to	Deposit Account 08-0380.		
				Respectfully submitted,	•		
				HAMILTON, BROOK, SMI	TH & REYNOLDS, P.C.		
				By Jesse A Fecker Registration No.: 52,883 Telephone: (978) 341-0036 Facsimile: (978) 341-0136			

Concord, MA 01742-9133 Dated: 7-9-03 PTO-1449 REPRODUCED

PRORMATION DISCLOSURE CITATION IN AN APPLICATION

Use several sheets if necessary)

JUL 1 4 2003 a July 8, 2003

ATTORNEY DOCKET NO. 1818.1030-003

APPLICATION NO. 10/066,320

APPLICANT

Jonathan S. Stamler, et al.

FILING DATE
January 31, 2002

confirmation no. 1921

GROUP 1654

THA	DEMMEN	U	S. PATENT DOCUMENTS	
EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME
	AA	6,203,789 B1	03/20/01	Stamler, et al. Stamler, et al. Stamler, et al.  Stamler, et al.  JUL 1 7 2003  TECH CENTER 1600/29
	AB	2003/0008300 A1	01/09/03	Stamler, et al. RECEIVE
-	AC	2002/0037839 A1	03/28/02	Stamler, et al. JUL 17
	AD			TECH 000
	AE			TECH CENTER 1600/20
	AF			
	AG			
	АН			
	AI			
	AJ			
	AK			
	AA2			
	AB2			
	AC2			
	AD2			
	AE2			
	AF2			
	AG2			
	AH2			
	AI2			
	AJ2			
	AK2			
	AA3			
	AB3			
	AC3			

EXAMINER	DATE CONSIDERED

O I PORTION DISCLOSURE CITATION IN AN APPLICATION

July 8, 2003

(Use several sheets if necessary)

ATTORNEY DOCKET NO. 1818.1030-003	APPLICATION NO. 10/066,320
APPLICANT	

Jonathan S. Stamler, et al.

FILING DATE
January 31, 2002

CONFIRMATION NO. GROUP
1921

1654

 FOREIGN PATENT DOCUMENTS							
	DOCUMENT NUMBER	DATE	COUNTE	RY	TRANSL YES	ATION NO	
 AL	WO 98/34955	13 Aug 98	PCT				
AM				TECH CEN	ECF	75	
 AN						ED	
 AO				TECHO	1720	03	
 AP				CEN CEN	TER 1800	/Oo -	
 AQ		]				2900	
AL2							
 AM2							
AN2							
AO2							
AP2						-	
AQ2							
AL3							
AM3							
AN3							
AO3							
 AP3							
AQ3					<u> </u>		
 AL4						ļ <u>.</u>	
AM4							
 AN4						<del> </del>	
 AO4						<del> </del>	
 AP4						<del>                                     </del>	
 AQ4						<del> </del>	
AL5					ļ	<del> </del>	
AM5					<u></u>	<u> </u>	

EXAMINER	DATE CONSIDERED

CDV4114/10/DN441/B441/ACE:407065:1			Sheet 3
PTO-1449 REPRODUCED	ATTORNEY DOCKET NO. 1818.1030-003	10/066,320	<u> </u>
O THE ORMATION DISCLOSURE CITATION IN AN APPLICATION	Jonathan S. Stamler, et al.		
July 8, 2003  July 8, 2003  July 8, 2003	FILING DATE January 31, 2002	confirmation no. 1921	GROUP 1654
			- <del></del>

.avd	ÿ¬
DEM	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
AR	Alayash, Abdu I., "Hemoglobin-based Blood Substitutes: Oxygen Carriers, Pressor Agents, or Oxidants?," Nature Biotechnology, 17:545-549 (1999).
AS	Alayash, Abdu I. et al., "Hemoglobin and Free Radicals: Implications for the Development of a Safe Blood Substitute," Molecular Medicine Today, 1:122-127 (1995).
AT	Ascenzi, Paolo et al., "Cooperative Effect of Inositol Hexakisphosphate, Bezafibrate, and Clofibric Acid on the Spectroscopic Properties of the Nitric Oxide Derivative of Ferrous Human Hemoglobin," <i>Journal of Inorganic Biochemistry</i> , 50:263-272 (1993).
AU	Cassoly, Robert <i>et al.</i> , "Conformation, Co-operativity and Ligand Binding in Human Hemoglobin," <i>Journal of Molecular Biology</i> , 91:301-313 (1975).
AV	Chétrite, Gérard et al., "Affinity of Hemoglobin for the Cytoplasmic Fragment of Human Erythrocyte Membrane Band 3," <i>Journal of Molecular Biology</i> , 185:639-644 (1985).
AW	Doherty, Daniel H. et al., "Rate of Reaction with Nitric Oxide Determines the Hypertensive Effect of Cell-Free Hemoglobin," <i>Nature Biotechnology</i> , 16:672-676 (1998).
AX	Eich, Raymund F. et al., "Mechanism of NO-Induced Oxidation of Myoglobin and Hemoglobin," Biochemistry, 35:6976-6983 (1996).
AY	Falke, Joseph J. et al., "Molecular Mechanisms of Band 3 Inhibitors. 1. Transport Site Inhibitors," <i>Biochemistry</i> , 25:7888-7894 (1986).
AZ	Falke, Joseph J. et al., "Molecular Mechanisms of Band 3 Inhibitors. 2. Channel Blockers," <i>Biochemistry</i> , 25:7895-7898 (1986).
AR2	Fox-Robichaud, Alison <i>et al.</i> , "Inhaled NO as a Viable Antiadhesive Therapy for Ischemia/Reperfusion Injury of Distal Microvascular Beds," <i>Journal of Clinical Investigation</i> , 101(11):2497-2505 (1998).
AS2	Galanter, William L. et al., "The Binding of Nitrate to the Human Anion Exchange Protein (AE1) Studied with <sup>14</sup> N Nuclear Magnetic Resonance," <i>Biochimica et Biophysica Acta</i> , 1079(2):146-151 (1991).
	AS  AT  AU  AW  AX  AY  AZ

	EXAMINER	DATE CONSIDERED
١		

PTO-1449 REPRODUCED	ATTORNEY DOCKET NO. APPLICATION NO. 1818.1030-003 10/066,320		
O INFORMATION DISCLOSURE CITATION IN AN APPLICATION	APPLICANT Jonathan S. Stamler, et al.		* , , ,
JUL 1 4 2003 July 8, 2003	FILING DATE January 31, 2002	CONFIRMATION NO. GROUP 1921 1654	

	Use several sheets if necessary)	January 31, 2002	1921	1654
TRADEMA				•
	OTHER DOCUMENT	S (Including Author, Title, Date, Perti	nent Pages, Etc.)	<del></del>
AT2	Gow, Andrew J. et al., "Reactions Between Nitric Oxide and Haemoglobin Under Physiological Conditions," <i>Nature</i> , 391:169-173 (1998).			
AU2	Gow, Andrew J. et al., "The Oxyhemoglobin Reaction of Nitric Oxide," Proceedings of the National Academy of Sciences USA, 96:9027-9032 (1999).			
AV	Hall, David M. et al., "Hyperthermia Stimulates Nitric Oxide Formation: Electron Paramagnetic Resonance Detection of •NO-Heme in Blood," <i>Journal of Applied Physiology</i> , 77(2):548-553 (1994).			
AW	Head, C. Alvin <i>et al.</i> , "Low Co Erythrocytes In Vitro and In V	oncentrations of Nitric Oxide livo," Journal of Clinical Inves	Increase Oxygen Af	ffinity of Sickle 93-1198 (1997).
AX	Hsu, Li et al., "The Interaction of Human Erythrocyte Band 3 with Cytoskeletal Components, Archives of Biochemistry and Biophysics, 227(1):31-38 (1983).			
AY	Jia, Li et al., "S-Nitrosohaemoglobin: A Dynamic Activity of Blood Involved in Vascular Control, Nature, 380:221-226 (1996).			
AZ	Kermarrec, Nathalie et al., "In Fibrinolysis in Rats with Endo Care Medicine, 158(3):833-83	toxic Lung Injury," American	on Platelet Aggrega Journal of Respira	ation and atory and Critical
AF	Liu, Xiaoping et al., "Diffusion of Biological Chemistry, 273:	n-limited Reaction of Free Ni 18709-18713 (1998).	tric Oxide with Ery	throcytes," <i>Journal</i>
AS	Low, Philip S., "Structure and Erythrocyte Membrane-Periph 167 (1986).	Function of the Cytoplasmic neral Protein Interactions," <i>Bio</i>	Domain of Band 3: ochimica et Biophys	Center of sica Acta, 864:145-
A	Marletta, Michael A. et al., "U 2:219-225 (1990).	Jnraveling the Biological Sign	nificance of Nitric C	Oxide," Biofactors,
A	McMahon, Timothy Joseph e Nitrosohemoglobin," Journal	t al., "Functional Coupling of of Biological Chemistry, 275	Oxygen Binding ar (22):16738-16745 (	nd Vasoactivity in S (2000).

EXAMINER	DATE CONSIDERED

PTO-1449 REPRODUCED NEORMATION DISCLOSURE CITATION IN AN APPLICATION JUL 1 4 2003 & July 8, 2003

Use several sheets if necessary)

ATTORNEY DOCKET NO. 1818.1030-003 APPLICANT

APPLICATION NO. 10/066,320

Jonathan S. Stamler, et al.

FILING DATE January 31, 2002 CONFIRMATION NO. 1921

GROUP 1654

IRA	DEMA			
	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	AV3	McMahon, Timothy J. et al., "Concerted Nitric Oxide/Oxygen Delivery by Hemoglobin," Methods In Enzymology, 301:99-114 (1999).		
	AW3	Moore, Edwin G. et al., "Cooperativity in the Dissociation of Nitric Oxide from Hemoglobin," Journal of Biological Chemistry, 251(9):2788-2794 (1976).		
	AX3	Okubo, Kenshi et al., "Red Blood Cell Band 3," Journal of Biological Chemistry, 269(3):1918-1926 (1994).		
	AY3	Pawloski, John R. et al., "Cell-Free and Erythrocytic S-Nitrosohemoglobin Inhibits Human Platelet Aggregation," Circulation, 97(3):263-267 (1998).		
	AZ3	Pietraforte, Donatella et al., "Role of Thiols in the Targeting of S-Nitroso Thiols to Red Blood Cells," <i>Biochemistry</i> , 34:7177-7185 (1995).		
	AR4	Rossaint, Rolf et al., "Inhaled Nitric Oxide for the Adult Respiratory Distress Syndrome," New England Journal of Medicine, 328(6):399-405 (1993).		
	AS4	Santos-Silva, Alice et al., "Altered Erythrocyte Membrane Band 3 Profile as a Marker in Patients at Risk for Cardiovascular Disease," <i>Atherosclerosis</i> , 116:199-209 (1995).		
	AT4	Soszynski, Miroslaw et al., "Penetration of Erythrocyte Membrane by Peroxynitrite: Participation of the Anion Exchange Protein," <i>Biochemistry and Molecular Biology International</i> , 43(2):319-325 (1997).		
	AU4	Stamler, Jonathan S. et al., "Blood Flow Regulation by S-Nitrosohemoglobin in the Physiological Oxygen Gradient," <i>Science</i> , 276:2034-2037 (1997).		
	AV4	Stamler, Jonathan S., "Redox Signaling:Nitrosylation and Related Target Interactions of Nitric Oxide," Cell, 78:931-936 (1994).		
	AW4	Stamler, Jonathan S. et al., "(S)NO Signals: Translocation, Regulation, and a Consensus Motif," Neuron, 18:691-696 (1997).		
	AX4	Sugrue, M.F. et al., "L-662,583 is a Topically Effective Ocular Hypotensive Carbonic Anhydrase Inhibitor in Experimental Animals," <i>British Journal of Pharmacology</i> , 99(1):59-64 (1990).		

EXAMINER	DATE CONSIDERED

GROUP 1654

PTO-1449 REPRODUCED	ATTORNEY DOCKET NO. 1818.1030-003	APPLICATION NO. 10/066,320
O PINEORMATION DISCLOSURE CITATION IN AN APPLICATION	APPLICANT Jonathan S. Stamler, et a	ıl.
JUL 1 4 2003 July 8, 2003 (Use several sheets if necessary)	FILING DATE January 31, 2002	confirmation no.
Can may		• . •

RADEMAR	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
AY4	Takahashi, Yuko et al., "Nitrosyl Hemoglobin in Blood of Normoxic and Hypoxic Sheep During Nitric Oxide Inhalation," American Journal of Physiology, 274(1):H349-H357 (1998).
AZ4	Vanin, Anatoly F. et al., "Iron Catalyzes Both Decomposition and Synthesis of S-Nitrosothiols:Optical and Electron Paramagnetic Resonance Studies," Nitric Oxide:Biology and Chemistry, 1(3):191-203 (1997).
AR5	Vaughn, Mark W. et al., "Erythrocytes Possess an Intrinsic Barrier to Nitric Oxide Consumption," Journal of Biological Chemistry, 275(4):2342-2348 (2000).
AS5	Walder, Joseph A. et al., "The Interaction of Hemoglobin with the Cytoplasmic Domain of Band 3 of the Human Erythrocyte Membrane," <i>Journal of Biological Chemistry</i> , 259(16):10238-10246 (1984).
AT5	Wessel, David L. et al., "Use of Inhaled Nitric Oxide and Acetylcholine in the Evaluation of Pulmonary Hypertension and Endothelial Function After Cardiopulmonary Bypass," Circulation, 88(5):2128-2138 (1993).
AU5	Wong, Bradley K. et al., "Dose-Dependent Pharmacokinetics of L-693,612, a Carbonic Anhydrase Inhibitor, Following Oral Administration in Rats," <i>Pharmaceutical Research</i> , 11(3):438-441 (1994).
AV5	Yonetani, Takashi <i>et al.</i> , "Electron Paramagnetic Resonance and Oxygen Binding Studies of α-Nitrosyl Hemoglobin," <i>Journal of Biological Chemistry</i> , 273(32):20323-20333 (1998).

EXAMINER	DATE CONSIDERED	